

PRODUCT: 7 vials of *liver-folic acid—B₁₂ injection* at Springfield, Mass. Analysis showed that the product contained less than 7 percent of the declared amount of vitamin B₁₂.

LABEL, IN PART: (Vial) "10 cc Multiple-Dose Vial Liver-Folic Acid B-12 H. P. Hematopoietic Formula For Treatment of Anemias * * * Each cc. contains: Vit. B-12 (Crystalline) 60 mcg."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each cc. contains: Vit. B-12 * * * 60 mcg."

Misbranding, Section 502 (a), the label statement "Each cc. contains: Vit. B-12 * * * 60 mcg." was false and misleading as applied to the article, which contained less than the declared amount of vitamin B₁₂.

DISPOSITION: November 10, 1952. Default decree of condemnation and destruction.

3910. Adulteration and misbranding of Nemaron capsules. U. S. v. 3 Buckets, etc. (F. D. C. No. 33339. Sample No. 46270-L.)

LIBEL FILED: July 9, 1952, Northern District of Alabama.

ALLEGED SHIPMENT: On or about February 4, 1952, by the Keith-Victor Pharmacal Co., from St. Louis, Mo.

PRODUCT: *Nemaron capsules*. 3 buckets, each containing 2,000 capsules and 26 bottles, each containing 25 capsules, 6 bottles, each containing 500 capsules, and 110 bottles, each containing 100 capsules, at Birmingham, Ala.

The capsules had been shipped in a bulk container, and were repackaged and relabeled by the consignee. Analysis showed that the product contained 60 percent of the declared amount of vitamin B₁₂.

LABEL, IN PART: (Bulk container) "Each Capsule Contains Vitamin B-12 25 Mcgs." and (buckets and bottles) "Nemaron A Therapeutic Potency Vitamin B-12 * * * Each Capsule Contains Vitamin B-12 20 Mcgs."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it was represented to possess, namely, "Each Capsule Contains Vitamin B-12 25 Mcgs."

Misbranding, Section 502 (a), the label statement "Each Capsule Contains Vitamin B-12 25 Mcgs." was false and misleading as applied to the product, which contained less than the declared amount of vitamin B₁₂.

DISPOSITION: December 22, 1952. Default decree of condemnation and destruction.

3911. Adulteration and misbranding of Enca Cream. U. S. v. 23 Gross Jars, etc. (F. D. C. No. 27212. Sample Nos. 46583-K, 46584-K.)

LIBEL FILED: May 13, 1949, Western District of Pennsylvania.

ALLEGED SHIPMENT: On or about September 24, 1948, and April 8, 1949, by Atlas Laboratories, Inc., from Akron, Ohio.

PRODUCT: 23 gross jars of *Enca Cream*, together with a number of booklets entitled "presenting New Facts about Acne and its associated Skin Blemishes," and a number of counter display cards and window streamers, at Pittsburgh, Pa.

LABEL, IN PART: (Jar) "Active Ingredients: Tyrothricin, resorcin, zinc oxide, petrolatum Distributed by Morton Products, Inc. Cleveland 14, Ohio."

NATURE OF CHARGE: Adulteration, Section 501 (c), the strength of the article differed from that which it purported and was represented to possess since it possessed no antiseptic properties against *Staphylococcus aureus* or *Staphylococcus pyogenes* micro-organisms commonly associated with skin infections, as stated and implied in the labeling.

Misbranding, Section 502 (a), certain statements on some of the cartons containing the jars of the article, in a booklet enclosed in some of the cartons, on the above-mentioned window streamers and display cards, and in a booklet accompanying the article were false and misleading. The statements represented and suggested that the article would be effective in the treatment of pimples, blackheads, and other externally caused minor skin blemishes, burning, itching skin, and acne and its associated skin blemishes. The article would not be effective in the treatment of the conditions stated and implied.

Further misbranding, Section 502 (a), the statements "Base for the new 'wonder formula' * * * non-greasy vehicle," "Enca's greaseless cream base," and "Enca is greaseless" appearing in the above-mentioned booklet accompanying the article were false and misleading as applied to an article which contained petrolatum, a grease; and certain other statements in the above-mentioned booklet were false and misleading since they represented and suggested that the article had antiseptic properties against organisms commonly found in skin infections, whereas the article possessed no antiseptic properties against *Staphylococcus aureus* or *Staphylococcus pyogenes* micro-organisms commonly associated with skin infections.

DISPOSITION: On July 1, 1949, the manufacturer of the product, Morton Products, Inc., Cleveland, Ohio, having petitioned for the removal of the libel action for trial in the Northern District of Ohio, the United States Court for the Western District of Pennsylvania entered an order providing for such removal. Following the removal, a motion to remand the case to the court of original jurisdiction was filed, on behalf of the Government, with the United States District Court for the Northern District of Ohio. On October 25, 1949, the court handed down the following decision providing for the remanding of the case:

JONES, *District Judge*: "This is a libel brought under favor of 21 U. S. C. A. Sec. 334 (Pure Food and Drug Act) for the condemnation of the product and advertising matter in the caption of this memorandum. Originally the action was commenced in the Western District of Pennsylvania. Morton Products, Inc., whose principal place of business is in this division, intervened as claimant of the goods and petitioned that Court to remove this action to this district. The Court allowed the motion and the action was transferred here. The Government objected at all times to the removal and now has filed a motion to remand the action to the court of original jurisdiction.

"Apparently this action was removed to this district under favor of Section 1404 Title 28 U. S. C. A. If that section applies, the action was properly transferred and the Government's motion must be overruled.

"The pertinent part of 1404 (a) is as follows: '* * * A district court may transfer any civil action to any other district where it might have been brought.'

"It is true that under Supreme Court decisions this action would be covered by the phrase 'any civil action,' but, by the clear and unambiguous words of the statute, such civil action cannot be transferred to a district where the action could not originally have been started.

"This libel having been brought under favor of 21 U. S. C. A. 334, the articles may be condemned 'In any district court of the United States within the jurisdiction of which the article is found.' Since the articles were found in the Western District of Pennsylvania this action only could be commenced in that district. It could not, under Section 334, have been brought in this

district. Since this is so and since Section 1404 (a) may only be used to transfer actions to districts where they could have been brought, it follows that Section 1404 (a) could not be used to transfer this action here.

"It should also be noted that Section 1404 (b) provides for transfer of *in rem* actions. However, the revisers' notes show that this section 1404 (b), was meant to apply only to removal of causes between divisions within districts and not to removal of actions between districts. Section 1404 (b), therefore, can have no application to this action.

"Since Section 1404 (a) does not apply, the special venue section of 21 U. S. C. A. does. This section allows removal in this type action to district courts 'of reasonable proximity to claimant's place of business.' This phrase has been interpreted to exclude the district or division in which claimant's principal place of business is found. (U. S. v. 600 Units, 60 F. Supp. 144; U. S. v. Six Dozen Bottles Dr. Peter Kurik, 55 F. Supp. 458; U. S. v. 26 Dozen Bottles Cervigards, 60 F. Supp. 626.) As this district is the claimant's principal place of business, it follows that this action has been removed to a district which has not been given authority under Section 334 to try the action.

"Claimant contends that even if this action is not properly here, that the Court cannot re-examine the order of the District Court of the Western District of Pennsylvania. The only case it cites, however, is one where the court, to which the action was removed over protest of defendant, had proper venue and jurisdiction to hear the action. In this cause, Section 334 does not permit this Court to hear the action. In U. S. v. 26 Dozen Bottles of Cervigards, 60 F. Supp. 626, the Court to which the action was improperly removed, remanded the action to the Court of original jurisdiction. There is adequate authority for remanding an action when it has been improperly transferred under 21 U. S. C. A. 334.

"This action will be remanded to the court of original jurisdiction."

An appeal from the above court decision was taken by the manufacturer to the United States Court of Appeals for the Sixth Circuit, and on May 31, 1950, the appeal was dismissed pursuant to the motion of the manufacturer.

The case was returned to the United States District Court for the Western District of Pennsylvania, and, on January 23, 1953, judgment of condemnation was entered and the court ordered that the product be destroyed.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FALSE AND MISLEADING CLAIMS*

3912. Action to enjoin and restrain the interstate shipment of misbranded Dunkler Cancer Test Reagents. U. S. v. William Dunkler (William Dunkler Laboratories). Consent decree granting permanent injunction. (Inj. No. 255.)

COMPLAINT FILED: October 29, 1952, Northern District of Illinois, against William Dunkler, trading as the William Dunkler Laboratories, Chicago, Ill.

NATURE OF CHARGE: That the defendant had been and was at the time manufacturing, preparing, packing, distributing, and selling drugs intended for use in the diagnosis of cancer and labeled, in part, "Dunkler Cancer Test Reagents I" and "Dunkler Cancer Test Reagents II"; that he had been and was at the time introducing and delivering, and causing the introduction and delivery, for introduction of the drugs into interstate commerce; and that the drugs were misbranded as follows:

Section 502 (a), the labelings contained statements which represented and suggested that the drugs constituted a reliable means of diagnosing cancer, which statements were false and misleading since they did not constitute a

*See also Nos. 3902-3906, 3908-3911.

reliable means of diagnosing cancer; Sections 502 (b) (1) and (2), the drugs failed to bear labels containing the name and place of business of the manufacturer, packer, or distributor, and accurate statements of the quantity of the contents; and, Section 502 (e) (1), the label of the "Dunkler Cancer Test Reagents II" failed to bear the common or usual name of the drug, ether.

The complaint alleged further that the continued introduction and delivery of the drugs into interstate commerce was dangerous to the public and could cause irreparable injury through failure to diagnose a cancerous condition, which failure might well lead to such delay in obtaining treatment that irreparable injury would occur; and that it was necessary that a temporary restraining order issue *ex parte*, pending hearing for a preliminary injunction.

The complaint prayed that the court grant a temporary restraining order restraining the defendant, his agents, servants, employees, representatives, and all persons in active concert or participation with him from directly or indirectly introducing or delivering the drug for introduction into interstate commerce; that an order be entered directing the defendant to show cause why the relief prayed for should not be granted; that upon the hearing of such order, a preliminary injunction be granted; and that after further due proceedings, such preliminary injunction be made permanent.

DISPOSITION: On October 30, 1952, the court issued a temporary restraining order, and on November 17, 1952, the defendant having consented to the entry of a decree, judgment was entered that the defendant be perpetually enjoined and restrained from directly or indirectly introducing or causing the introduction or delivery into interstate commerce of articles of drugs misbranded within the meaning of Section 502.

3913. Misbranding of calcium pantothenate tablets. U. S. v. 14 Bottles * * *.
(F. D. C. No. 26950. Sample No. 48288-K.)

LIBEL FILED: March 25, 1949, District of Delaware.

ALLEGED SHIPMENT: On or about September 24, 1948, from Newark, N. J.

PRODUCT: *Calcium pantothenate tablets.* 14 bottles, each containing 100 tablets, in the possession of the Natural Food Centre, Wilmington, Del. The product was shipped in bulk containers, and was bottled and labeled by the consignee, the Natural Food Centre.

LABEL, IN PART: (Bottle) "Daland's Calcium Panto-Thenate Tablets."

NATURE OF CHARGE: Misbranding, Section 502 (a), the statement appearing on the bottle label "Clinical experiments have shown darkening of the hair in some cases in 1 month, others in 23 months to a year" was false and misleading since it represented and suggested that the article was effective to restore the original color to gray hair, whereas it was not effective for such purpose. The article was misbranded while held for sale after shipment in interstate commerce.

DISPOSITION: November 27, 1951. Judson D. Ryon, claimant, trading as the Natural Food Centre, having admitted the allegations of the libel and consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the product be destroyed.

3914. Misbranding of lecithin. U. S. v. 14 Drums, etc. (F. D. C. No. 33301.
Sample Nos. 37644-L, 37645-L.)

LIBEL FILED: June 23, 1952, Southern District of New York.